

This listing of claims will replace all prior versions, and listings, of the claims in the application:

Listing of Claims:

Claim 1. (Currently Amended) A pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is beta-cyclodextrin.

Claim 2. (Originally Presented) The pharmaceutical composition of claim 1, wherein the pharmaceutical composition comprises a complex or solution of the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule.

Claims 3-5. (Cancelled)

Claim 6. (Currently Amended) The pharmaceutical composition of claim 1 5, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

Claims 7-8. (Cancelled)

Claim 9. (Currently Amended) The pharmaceutical composition of claim 1 3, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

Claim 10. (Cancelled)

Claim 11. (Currently Amended) A pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is beta-cyclodextrin, which when diluted with an aqueous solution for parenteral administration, remains substantially soluble in the aqueous solution.

Claim 12. (Currently Amended) The pharmaceutical composition of claim 11, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, is complexed with the pharmaceutically acceptable ~~water~~ solubilizing carrier molecule.

Claims 13-14. (Cancelled).

Claim 15. (Currently Amended) The pharmaceutical composition of claim 11 14, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

Claim 16-17. (Cancelled).

Claim 18. (Originally Presented) The pharmaceutical composition of claim 11, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

Claim 19. (Originally Presented) The pharmaceutical composition of claim 12, wherein the complex comprises a dosage unit in the range between 0.1 mg/kg to 10 mg/kg administered from between twice weekly to once every four weeks.

Claim 20. (Cancelled).

Claim 21. (Currently Amended) A formulation of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is beta-cyclodextrin, wherein the formulation can be freeze-dried and when subsequently reconstituted in aqueous solution is substantially soluble.

Claim 22. (Originally Presented) The formulation of claim 21, wherein the Beta-lapachone, or a derivative or analog thereof is complexed with the pharmaceutically acceptable solubilizing carrier molecule.

Claims 23-24. (Cancelled).

Claim 25. (Currently Amended) The formulation of claim 21 24, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

Claims 26-27. (Previously Cancelled).

Claim 28. (Originally Presented) The formulation of claim 21, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

Claim 29. (Cancelled).

Claim 30. (Originally Presented) A kit for the treatment of a mammalian cancer comprising at least one vial containing Beta-lapachone, or a derivative or analog thereof, according to any one of claims 1, 11 or 21.

Claim 31. (Currently Amended) A pharmaceutical composition comprising a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is beta-cyclodextrin, and further comprising a second anticancer agent and a pharmaceutically acceptable carrier.

Claim 32. (Originally Presented) The pharmaceutical composition of claim 31, wherein the composition comprises a complex or solution of the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule, and further comprises the second anticancer agent and a pharmaceutically acceptable carrier.

Claim 33. (Originally Presented) The pharmaceutical composition of claims 31 or 32, wherein the second anticancer agent is a taxane derivative.

Claim 34. (Originally Presented) The pharmaceutical composition of claim 33, wherein the taxane derivative is paclitaxel.

Claim 35. (Cancelled).

Claim 36. (Originally Presented) The pharmaceutical composition of claim 31, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule is admixed with the second anticancer agent and the pharmaceutically acceptable carrier and contained in a single vial.

Claim 37. (Originally Presented) The pharmaceutical composition of claim 31, wherein the therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and the pharmaceutically acceptable solubilizing carrier molecule is contained in a first vial, and the second anticancer agent and the pharmaceutically acceptable carrier are contained in a second vial.

Claims 38-39. (Cancelled).

Claim 40. (Currently Amended) The pharmaceutical composition of claim 31 39, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

Claims 41-42. (Cancelled).

Claim 43. (Currently Amended) The pharmaceutical composition of claim 31 35, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

Claim 44. (Cancelled).

Claim 45. (Currently Amended) A kit for the treatment of a mammalian tumor comprising one or more vials containing a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is beta-cyclodextrin and further comprising, within the same vial or a separate vial, a second anticancer agent.

Claim 46. (Originally Presented) The kit of claim 45, wherein the one or more vials contain a complex of the therapeutically effective amount of Beta-lapachone, or a derivative or analog

thereof, and the pharmaceutically acceptable solubilizing carrier molecule and further comprising, within in the same vial or a separate vial, the second anticancer agent.

Claim 47. (Originally Presented) The kit of claims 45 or 46, wherein the second anticancer agent is a taxane derivative.

Claim 48. (Originally Presented) The kit of claim 47, wherein the taxane derivative is paclitaxel.

Claims 49-50. (Cancelled).

Claim 51. (Currently Amended) The kit of claim 45 50, wherein the beta-cyclodextrin is hydroxypropyl-beta-cyclodextrin.

Claims 52-53. (Cancelled).

Claim 54. (Originally Presented) The kit of claims 45 or 46, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

Claims 55-80 (Cancelled).

Claims 81-82 (Previously Cancelled).

Claims 83-122 (Cancelled).

Claims 123-124 (Previously Cancelled).

Claims 125-179 (Cancelled).

Claim 180. (Currently Amended) A sterile injectable pharmaceutical composition for intravenous administration comprising a complex of a therapeutically effective amount of Beta-lapachone, or a derivative or analog thereof, and a pharmaceutically acceptable water-solubilizing carrier molecule, wherein said solubilizing carrier molecule is beta-cyclodextrin.

Claim 181. (Cancelled)

Claim 182. (Currently Amended) The sterile injectable pharmaceutical composition of claim 180, wherein the pharmaceutically acceptable, ~~water~~ solubilizing carrier molecule is hydroxypropyl-beta-cyclodextrin.

Claim 183. (Originally Presented) The sterile injectable pharmaceutical composition of claim 180, further comprising a second anticancer agent and a pharmaceutically acceptable carrier.

Claim 184. (Originally Presented) The sterile injectable pharmaceutical composition of claim 183, wherein the second anticancer agent is a taxane derivative.

Claim 185. (Originally Presented) The sterile injectable pharmaceutical composition of claim 184, wherein the taxane derivative is paclitaxel.

Claim 186. (Originally Presented) The sterile injectable pharmaceutical composition of claim 180, wherein the concentration of Beta-lapachone in solution is at least 1 mg/ml.

Claims 187-203. (Cancelled).

Claim 204. (Newly Added) The pharmaceutical composition of claim 1, wherein the composition comprises a therapeutically effective amount of Beta-lapachone and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is beta-cyclodextrin.

Claim 205. (Newly Added) The pharmaceutical composition of claim 11, wherein the composition comprises a therapeutically effective amount of Beta-lapachone and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is beta-cyclodextrin, which when diluted with an aqueous solution for parenteral administration, remains soluble in the aqueous solution.

Claim 206. (Newly Added) The formulation of claim 21, wherein the formulation comprises Beta-lapachone and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is beta-cyclodextrin, wherein the formulation can be freeze-dried and when subsequently reconstituted in aqueous solution is soluble.

Claim 207. (Newly Added) The pharmaceutical composition of claim 31, wherein the composition comprises a therapeutically effective amount of Beta-lapachone and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is beta-cyclodextrin, and further comprising a second anticancer agent and a pharmaceutically acceptable carrier.

Claim 208. (Newly Added) The kit of claim 45, wherein the kit comprises one or more vials containing a therapeutically effective amount of Beta-lapachone and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is beta-cyclodextrin and further comprising, within the same vial or a separate vial, a second anticancer agent.

Claim 209. (Newly Added) The sterile injectable pharmaceutical composition of claim 180, wherein the composition comprises a complex of a therapeutically effective amount of Beta-lapachone and a pharmaceutically acceptable solubilizing carrier molecule, wherein said solubilizing carrier molecule is beta-cyclodextrin.